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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,126	12/12/2001	Connie Sanchez	5432/0J951US0	7268

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DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/21/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/021,126

Applicant(s)

SANCHEZ ET AL.

Examiner

Frederick Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Election of Species Requirement

Applicant's election of the particular pathology "panic attacks" in Paper no. 8 is noted.

Claims 6-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 10, 11 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Lepola et al ("A Controlled, Prospective, 1-Year Trial of Citalopram in the Treatment of Panic Disorder", *J. Clin. Psychiatry*, 59:10, pp. 528-534 (October 1998)).

The prior art discloses the use of racemic citalopram to treat panic attacks associated with panic disorder or agoraphobia (page 529, righthand column, second paragraph). The active agent is administered in unit dosage form in amounts ranging from 10 to 60mg/day (second paragraph of the article).

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The instant claims recite the treatment of neurotic disorders with escitalopram, i.e. the (+) isomer, but do not specify any degree of optical purity. Furthermore, they use the open-ended transitional phrase "comprising". Accordingly, they do not exclude the inclusion of the (-) isomer, and read upon racemic citalopram. Consequently, they are anticipated by the prior art.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 1-5, 10, 11 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over Lepola et al in view of Boegesoe et al (U.S.P. 4,943,590).

For the sake of completeness of prosecution and with respect to this rejection only, it will be assumed purely *arguendo* that the instant claims are limited exclusively to the (S) isomer of citalopram.

The primary reference has been discussed in the "Anticipation" rejection supra. Adopting the premise set forth above purely *arguendo*, the primary reference would differ from the instant claims insofar as it discloses the use of racemic citalopram, which includes the (-) isomer.

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The secondary reference teaches that the activity of citalopram resides entirely with the (+) isomer. (col. 2, lines 38-40). It differs from the instant claims insofar as it specifies the treatment of depression rather than neurotic disorders.

It would have been obvious to have used the isolated (+) isomer of citalopram, rather than racemic citalopram to treat panic attacks as disclosed by the primary reference, because the activity of the racemate (for psychiatric disorders, at least) resides entirely within the (+) isomer as taught by the secondary reference. The motivation to do so would be provided by the expectation of improved therapeutic efficacy and lessened side effects, which would be expected upon eliminating the undesirable (-) isomer. Further, given these facts, improved performance cannot be deemed an "unexpected result" in this case.

2) Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over Lepola et al.

The prior art has been discussed in the "Anticipation" rejection supra. It differs from the instant claims insofar as it does not specifically disclose the treatment of panic attacks associated with specific phobias or social phobias.

Lepola et al do, however, disclose the treatment of panic attacks associated with panic disorder and agoraphobia, as previously discussed. They also teach that panic disorders are "a heterogenous group of psychiatric symptoms characterized by fears and worries, nervousness, spells of terror or panic" (page 528, righthand column, first paragraph). These facts, considered in their entirety, reasonably suggest that citalopram

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is useful for the treatment of the underlying etiology of panic attacks generally, independent of associated symptoms. Accordingly, it would have been obvious to have treated panic attacks associated with specific phobias or social phobias, motivated by the reasonable expectation of therapeutic efficacy which can be fairly inferred from the prior art teachings.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (703) 308-4335. The examiner can normally be reached on Monday, Tuesday and Thursday from 9am to 5pm, and on Friday from 11am to 7pm. The examiner is off Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

Frederick Krass
Primary Examiner
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